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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,474	10/17/2001	Wilhelmus Theodorus Antonius Maria De Laat	246152012710	8056

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EXAMINER
WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/27/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/982,474	De Laat et al.
Examiner	**Art Unit**
Randall Winston	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8, 15, 16, 19, 20, 36, and 37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8, 15, 16, 19, 20, 36, and 37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on June 8, 2002.

Claims 1-8, 15-16, 19-20 and 36-37 are under examination.

The rejection made under 35 U.S.C. 112, second paragraph, set forth in the previous office action has been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 102 set forth in the previous office action has been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 15-16, 19-20, and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "utilizes only." One of ordinary skill in the art would not know how to interpret whether the fermentation medium utilizes only chemical defined components or does the fermentation medium also utilizes a mutant strain.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 15-16, 19-20, and 36-37 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hogye et. al. (Derwent 1987-357537) in view of Bovenberg et al. (US 5731165) and Microbiology, fourth edition, Pelczar, Reid, and Chan pages 853-856.

Applicants argue that neither Hogye nor Bovenberg, alone or in combination, in any way suggest the process of claim 1 which requires a minimum volume of 10 m3 in combination with a chemically defined medium. As claim 1 is not suggested, the putatively obvious variations set forth in claims 5-8 are not suggested either, nor is the subject matter of any of dependent claims suggested thereby. Accordingly, this basis for rejection may also be withdrawn. Applicants' arguments, however, are not found persuasive since one of ordinary skill in the art would have been motivated to modify Hogye et al.'s process to include Bovenberg et al.'s process for the beneficial purpose of producing the claimed invention's process of the production of penicillin V and/or adipoyl-7-ADCA because both process utilize the same steps to produce different Beta-Lactams, it would also be an obvious benefit to one of ordinary skill in the art to industrially mass produce Beta-Lactam (i.e. a penicillin) utilizing the claimed invention's standard

chemically defined medium because Microbiology, pages 853-856, teaches that penicillin was the first antibiotic to be produced industrially utilizing a similar standard chemically defined medium as the claimed invention's chemically defined medium (see, especially, e.g., page 855-856, the steps).

Furthermore, applicants' inclusion of the phrase "components as carbon and nitrogen sources and contains no complex raw materials" within claim 1 furthered defined in claim 3 is not found persuasive because Microbiology, pages 853-856, teaches it is common to add other chemicals (i.e, carbon and nitrogen sources) to a chemically defined medium for the production the Beta-Lactam (i.e. a pencillin) (see, e.g., page 855, step 5, states the additions of chemicals to the medium serves as precursors for synthesis of penicillin.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER